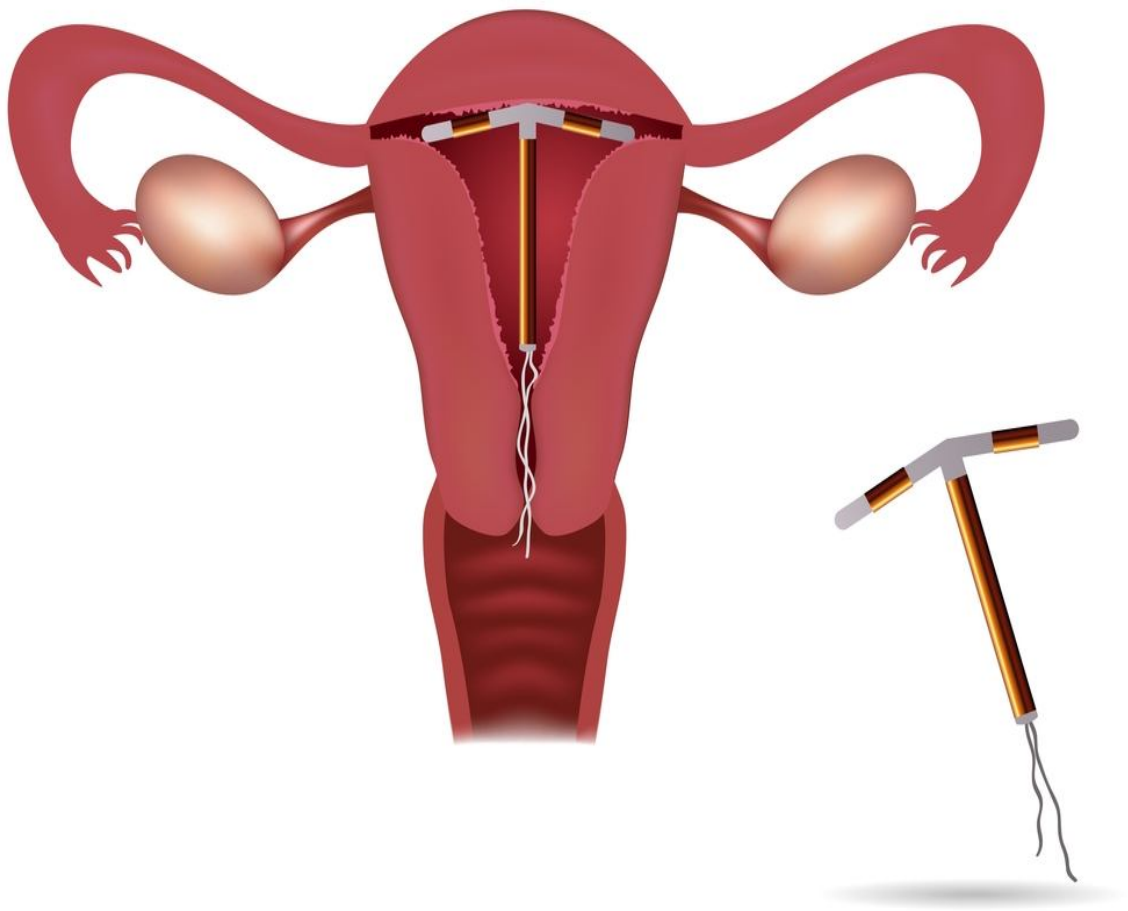


EFFICACY AND SAFETY OF POST PARTUM INSERTION OF IUCD AMONG PARTURITENTS



EFFICACY AND SAFETY OF PPIUCD AMONG PARTURITENTS

ABSTRACT

Aim:To determine the safety and efficacy of postpartum insertion of IUCD among parturitents.

Methods: CuT 380A were inserted within 10 min after postplacental expulsion and 48 hours post partum both in vaginal and cesarean deliveries based on the medical eligibility criteria. Out of 300 woman, only 259 returned for follow up..They are given education regarding complications at discharge and counselled for follow up at 3 months and 6months and at 12months.

Results:The follow up rate at 3months, 6 months and at 12 months are 72.6%,76.3%, 74.3% respectively.The continuation rates at 6& 12 months are- 95.6%, 93.2% respectively. There are no pregnancy nor perforations at the end of 1 year. The discontinuation rate means it includes both spontaneous expulsion and removal due to medical problems.The annual cumulative expulsion rate 2% and the annual removal rate 2.3%.

Conclusion: The evidence from this study suggests that immediate postplacental insertion of CuT 380A is an effective, useful, safe, convenient and low-cost procedure for early postpartum contraception

Keywords: Intrauterine device; Postplacental insertion

CONTENT

S.No.	TITLE	PAGE No.
1.	INTRODUCTION	3
2.	REVIEW OF LITERATURE	9
3.	AIM OF STUDY	17
4.	MATERIALS AND METHODS	18
5.	RESULTS AND ANALYSIS	32
6.	DISCUSSION	73
7.	SUMMARY	77
8.	CONCLUSION	80
9.	BIBLIOGRAPHY	82
10.	ABBREVIATIONS	
11.	ANNEXURE-I PROFORMA	
12.	ANNEXURE-II MASTER CHART	

INTRODUCTION

The intrauterine contraceptive device is one of the most widely used method of reversible fertility regulation with more than hundred million users worldwide.

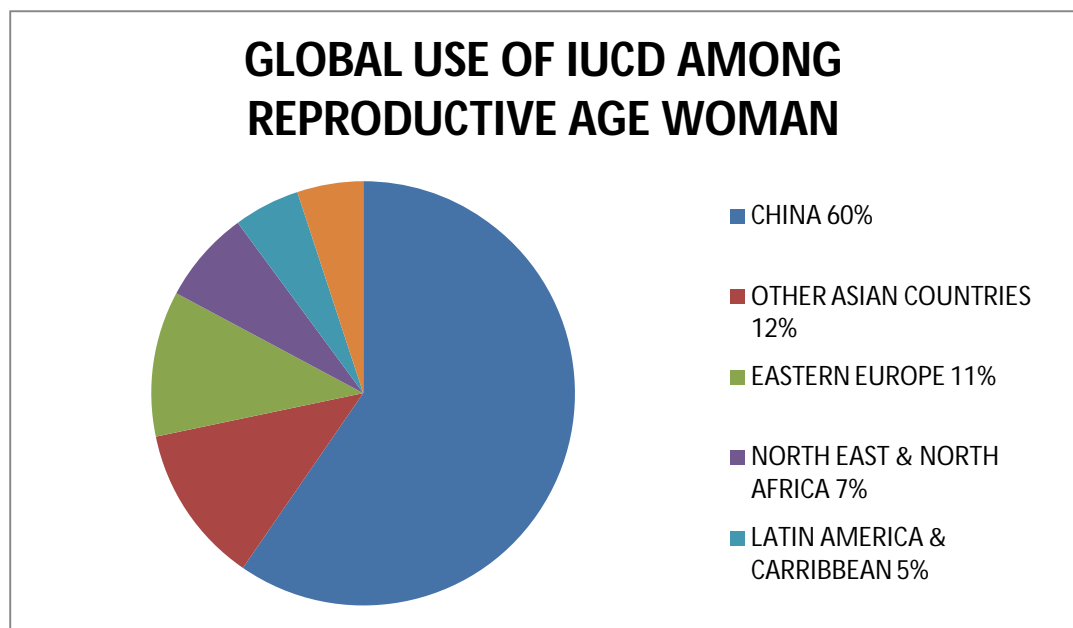
The population in India has been growing rapidly which will reach 1.53 billion by 2050. Approximately 248 million women belong to the age group of 15-49 years. The main objective of the family planning program is to promote adequate spacing of births, by providing high quality of contraceptive services.

According to NFHS –3, the prevalence rate of birth control in India is 56.3 %, and the unmet need is high (13%) with 6% for spacing.

Review of literature have showed that IUCDs are very effective, safe and offers long-term protection against pregnancy with negligible health risks.

Global use of IUCD

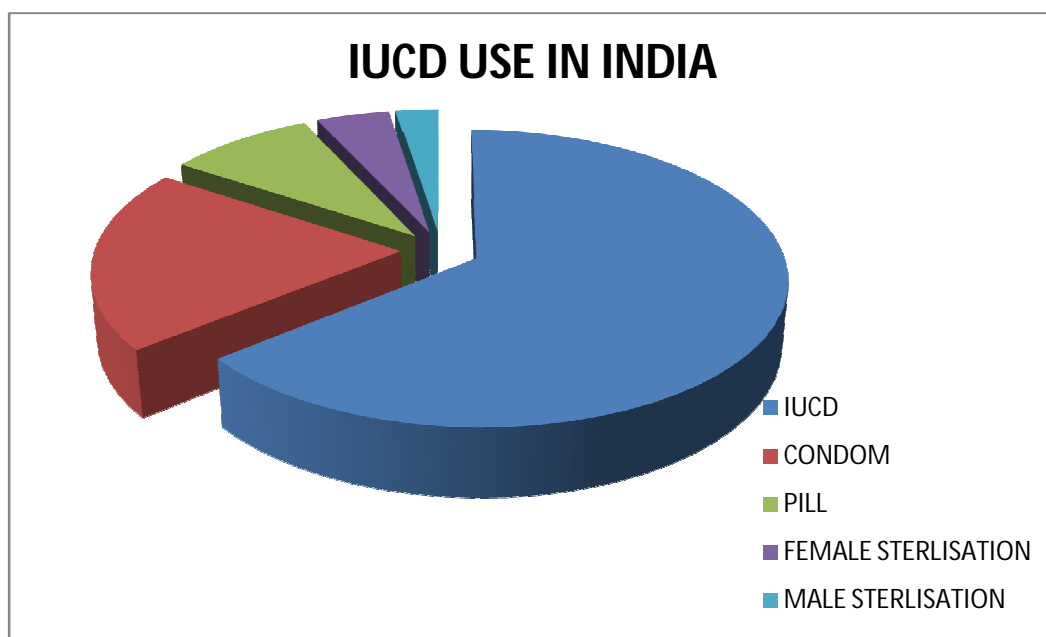
Recent data shows that almost one in every five married couples are using an IUCD.



Indian scale of IUCD

Earlier in 1965 ,the Government of India, introduced Lippes Loop,which was considered as an important spacing method. Later on the as per the results of clinical trials conducted by the Indian Council of Medical Research in 1972, Copper T 200 B was introduced in 1975. In 1997, ICMR again conducted a comparative study between IUCD 200B and 380A as CuT 380A was introduced in2002, which had replaced CuT 200B in that programme.

Now the government is offering IUCD services free of cost, under JHPIEGO(Johns Hopkins program for international education in Gynaecology & obstetrics), which was implemented in 2009,it still remains largely underutilized.



INTRA UTERINE CONTRACEPTIVE DEVIC

The IUCD was first introduced by Graffenberg in 1909. Subsequently, Jack Lippes developed the Lippes Loop in the 1960s , which became the most commonly used IUCD in many countries.

When Copper T IUCD 380 A came into being, it has become one of the best known and most widely used IUCDs in the world which is available in many countries. It is a T shaped device made up of polyethylene and impregnated with barium sulfate to render it radio opaque for visibility on X-ray. It is 3.6 cm in length and 3.2 cm in width. The copper wire is wound around in each horizontal arm as well as in the vertical stem. copper is released high in the fundus of the uterus at the rate of 50µg/day . A thin polyethylene string is attached to the bottom of the stem for easy removal.

MECHANISM OF ACTION

Copper T 380A, acts primarily by preventing fertilization. The released Copper decreases sperm motility and alters the enzymatic and metabolic changes in the uterus and fallopian tube, there by preventing sperm from reaching the fallopian tubes and fertilizing the ovum. It also

also stimulates foreign body reaction in the endometrium that causes macrophage release and prevents implantation of the fertilized ovum.

The effectiveness is dependent on the annual failure (pregnancy) rate. Copper T380 A has an effective life of upto 10 years. A woman's fertility returns immediately after an IUCD is removed .

ADVANTAGES

- Convenient for the woman as it saves time and no additional visits are needed, as well as for the inserter for the easy integration of services.
- Safe because it is certain that she is not pregnant at the time of insertion
- High motivation from both woman and family is needed.
- Risk of uterine perforation is negligible because of the thick wall of the uterus.
- Decreased perception of initial side effects like bleeding and cramping.
- Doesn't affect the amount or quality of breast milk
- It is very effective and is immediate
- Provides a healthy birth spacing interval, there by reduces morbidity and mortality of mother and newborn. If the birth to

pregnancy interval is < 6 months, there is increased risk of miscarriage, induced abortion, and maternal mortality. Birth to pregnancy interval of < 24 months are associated with higher infant neonatal mortality.

- A single decision is enough to provide long-term prevention of pregnancy.
- There are no hormonal side effects with copper-bearing IUCD.
- Risk of ectopic pregnancy are minimal than in women not using any family planning method.
-

LIMITATIONS

- Increased risk of spontaneous expulsion
- Spontaneous expulsion rates for PPIUCD are dependent upon insertion technique and the skill of the provider.

The rate of expulsion vary widely in the range of 10 – 14%. A well skilled inserter and the insertion technique reduces expulsion rates to 2 – 5%.

REVIEW OF LITERATURE

1. Ory HW, for Women's Health study , Showed there is 80%-90% reduction in the risk of ectopic pregnancy due to higher dose of copperT380A
2. The Oxford study Vessey M, Doll R, Peto R , et al ,Found that women gave birth just as promptly after IUCD removal as they did after discontinuing use of the diaphragm.
3. A Cochrane data base – Grimes DA, Lopez LM et al 2006, The discontinuation for pain and bleeding is higher with copper IUCD. The worsened periods often occur with the first few menses and they are treated with NSAID'S.
4. A Cochrane Database- Celen S , Sucak A et al 2004, Clinical outcomes in early postplacental insertion of IUCD.It appears to be safe, effective and there were no bleeding, infection nor perforation The main disadvantage was increased expulsion , and it was 12.3% at 1 year with the copper T.

5. A Randomised control trial Trussel et al 2004, Showed insertion of IUCD after immediate postpartum period and before 4 weeks postpartum was associated with more perforations. Therefore it should be inserted within 10 minutes of placental delivery or after 4 weeks. the failure (pregnancy) rate of 0.8% at the end of 1 year of use.
6. Walsh T, Grimes D, Frieziers R, Randomised Control Trial of prophylactic antibiotics before insertion of IUCD-1998. No role in lowering the peri-insertion infections.
7. Rosenberg MJ, Waugh MS, A prospective evaluation of discontinuation between oral contraception and IUCD 1998, The continuation rate at the end of 1 year for Copper T 380A- 78%, OCP- 50%.
8. French R, Van Vliet H, Cowan F et al 2004- A Cochrane Database of pregnancy rates. The pregnancy rates at end of 1 year, CopperT 380 A- 0.8-0.6 and LNG IUS- 0.1. per 100 woman years.
9. Otero- Flores JB, Guerrero- Carreno FJ, Vazquez-Estrada LA 2003. A large Comparative Randomised Control Study of three different IUCD in nulliparous Mexican woman, The high

effectiveness with a failure rate at 1year and overall expulsion rates were 1.8%- T Null and multiload, compared with CopperT 380A- 3.3%.

10.Hubacher D, Grimes DA 2005.In a recent cohort study of 2,037,883 woman years of follow up in china was associated with a decreased risk of endometrial cancer with an adjusted odds ratio of 0.6 (95% CI 0.3-0.9).although type of IUCD were not specified, it was a combination of Copper T380A, and stainless steel rings were most frequently used device.

11.Cole et al,Expulsions in Immediate Postpartum Insertions of Lippes Loop D and Copper T IUDs and their Counterpart Delta Devices-- An Epidemiological Analysis1984. They have founded that postpartm insertion to be a safe procedure. the magnitude of IUD expulsions in postpartum depend upon the insertor's skill & experience.

12.Comparitive study between two techniques used in immediate postplacental insertion of TCu 380A in china : Chen Y yang X et al 1999 . This is a 36-month follow-up study which comprises 384

women who delivered vaginally and copper T-380A IUD was inserted within 10 minutes after delivery. A total of 189 IUDs were inserted by hand; 195 were inserted by ring forceps. Expulsion and other discontinuation rates were compared at 6, 12, 24, and 36 months post-insertion. There are no uterine perforation nor infection. There were 67 cases of expulsion, which was the main reason for the discontinuation. The gross cumulative expulsion rates for the manual insertion group after 6, 12, 24, and 36 months were 8.61, 13.55, 15.78, and 16.90 per 100 women, respectively. The gross cumulative expulsion rates for the ring forceps insertion group were 12.99, 17.23, 17.77, and 18.34 per 100 women, respectively. The differences between the two groups were not statistically significant.

13. A women's Health study – Kriplani A, Buckshee K, Relan S, et al, showed the only pelvic infection that has been unequivocally related to IUCD use is actinomycosis and that occurred in the women who have multiple sexual partners. The rate increases with duration of use of plastic devices, and it is much less for copper releasing IUCD's.

14. O'hanley K, Huber Dh April 2007, New York. Insertion at immediate postplacental and postpartum periods are demonstrably safe, because they have a low incidence of infection, few bleeding problems, and low perforation rates.

In their study expulsion rates of about 7-15 per 100 users at six months in a well experienced and a skilled inserter. Most investigators have found that high fundal IUD placement will reduce the expulsion rate. Unplanned pregnancy rates range from 2.0-2.8 per 100 users at 24 months with modern copper IUDs. It appears that manual or ring forceps insertion result in very low perforation rates, e.g., 1/1150 immediate postpartum IUD insertions in 1 study.

15. In studies comparing immediate postpartum IUD insertions with interval insertions, the removal rate due to bleeding is lower for the immediate postpartum IUD insertions, e.g., 13.7% vs. 23.6% in a study in India. 90-95% of women are able to detect their own expulsions.

16. Randomised comparative study between immediate postpartum insertion of multiload Cut375 and Cut380A Lara ricalde et al 2006-

The expulsion rates were 10.4 for the MLCu 375 and 7.7 for the TCu 380A . The removal rates for bleeding and pain were 4.9 and 4.8, the removal rates for non medical reasons were 3.7 and 4.9 respectively. There was one case of genital infection in the MLCu 375 group. There were no pregnancies, nor uterine perforation. The one year continuation rates were 77.1 and 82.6 respectively. There were no statistical significant differences in the comparative rates.

17. Randomised comparative study of two techniques used in immediate postplacental insertion of the Copper T-380A IUD in Shanghai, Rivera R et al, 1996-: IUD inserted by hand and IUD via ring forceps. Expulsions were the main reason for discontinuation. The six-month gross cumulative expulsion rates were 13.3 and 12.7 per 100 women in the hand-insertion group and ring forceps-insertion group, respectively.

Discontinuation rates for medical removals (bleeding/pain) were 2.1 and 1.0 in these two groups, respectively. Neither of the differences was statistically significant ($p > 0.05$). No uterine perforation, infection or pregnancy occurred.

18. The IUD expulsion rate was higher in non-breast feeding women than in breast-feeding women (22.4% vs. 11.9%; $p = 0.05$).

19. Comparison of efficacy and complications of IUD insertion in immediate postplacental/early postpartum period with interval period: 1 year follow-up. Taskin L haberal A et al 2006. This study aimed to compare immediate postplacental and early postpartum insertions with interval IUD insertions with respect to efficacy and complications. The study group consisted of 268 women in whom the following TCu 380A IUD insertions were performed: 84 (less than 10 min), 46 (10 min to 72 h) and 138 (more than 6 weeks). The women were followed up 8 weeks, 6 months and 12 months after insertion. Although no statistically significant difference was found between the groups for uterine perforation and infection ($p > .001$), there was a statistically significant difference between the groups in the incidence of expulsion rates.

The overall cumulative pregnancy rate and frequency of pregnancy were found to be higher ($p > .05$ for both), which are both insignificant for the EP group (2 of 43 women), as compared with the INT (4 of 130 women) and IPP groups (2 of 84 women), and pregnancy rates at 1 year for all groups was 3.1% (8 of 257

women). Immediate & early postpartum insertions are effective and convenient procedure but the expulsion rates are higher than in the interval insertion group.

20. In a longitudinal international study which was conducted by the WHO, where the average annual pregnancy rate was 0.4%, and the average cumulative pregnancy rate was 2.2% at the end of 12 years of use of CuT 380A, which is very similar to that of tubal sterilization (United Nations Development Programme et al. 1997).

AIM OF STUDY

To determine the safety and efficacy of postpartum insertion of IUCD among parturients.

MATERIALS AND METHODS

TYPE OF STUDY:

A descriptive longitudinal study among parturitents

DURATION OF STUDY:

November 2012 to October 2013

MATERIALS & METHODS:

This is a hospital based prospective study conducted at Institute of social obstetrics and Government kasturba Gandhi hospital for women and children, Triplicane, Chennai-5 from November 2012 to October 2013.

This study comprises study subject of 300 parturitents, who are willing for postpartum insertion of IUCD after getting written informed consent. The Chi-square test was used for the evaluation of the data.

INCLUSION CRITERIA:

All woman who were delivered in the study period

EXCLUSION CRITERIA:

1. Those woman who were delivered not willing for PPIUCD
2. Fever during labour
3. Premature rupture of membranes for more than 12 hours.
4. Chorioamnionitis
5. Active lower genital tract infections
6. AIDS
7. Allergy to copper
8. Uterine anamolies
9. Uterine abnormalities like myoma uterus
10. Manual removal of placenta
11. Post partum haemorrhage-uterine atony, traumatic

MEDICAL ELIGIBILITY CRITERIA

It describes IUCD use for women under specific medical conditions. The reproductive rights of the individual must be considered. It is essential that the provider has to screen the women based on the MEC in order to provide the quality care in IUCD services. There are four categories.

CATEGORY 1: Can use the IUCD with no restrictions.

- less than 48 hours postpartum
- Age: greater than 20 years
- Parity 1 or more
- Irregular menstrual cycles without heavy menstrual bleeding
- Cigarette smoking
- Obesity
- History of hypertension
- Previous history of Thromboembolic disease
- Hyperlipidemias
- Uncomplicated valvular heart disease
- Epilepsy
- Depression
- Benign ovarian tumors
- Cervical intraepithelial neoplasia
- Benign breast disease or breast cancer
- Women taking antibiotics or anticonvulsants
- Thyroid, liver or gallbladder disease or diabetes
- Malaria
- Non-pelvic tuberculosis

- History of a prior ectopic pregnancy
- Previous history of pelvic inflammatory disease
- Previous caesarean section.

CATEGORY 2: IUCD used with caution. It means that advantages generally outweigh the risks, so additional care/follow-up will be needed

- From age of menarche to <20 years,
- Nulliparity
- Heavy or prolonged vaginal bleeding
- Anatomical abnormalities that do not distort the uterine cavity
- Any active lower genital tract infection should be treated, and then inserted
- Have a past history of PID without a subsequent pregnancy.
- Clinically well HIV infected women
- Symptomatic AIDS women, on antiretroviral therapy
- Immediately following a second-trimester abortion either spontaneous or induced with no evidence of infection.
- Complicated valvular heart disease e.g., artificial shunts, rheumatic heart disease. prophylactic antibiotics are given to prevent endocarditis.
- Anemic women, as copper-bearing IUCDs are associated with increased menstrual blood loss.
- Women with 1st and 2nd degree uterine prolapse
- Rectovaginal fistula

CATEGORY 3: IUCD use is not recommended as risks generally outweigh the advantages.

- Heavy/prolonged menstruation, endometriosis, or severe dysmenorrhea.
- After 48 hours to 6 weeks postpartum.
- Benign trophoblastic disease.
- Ovarian cancer
- Women with multiple sexual partners as they are at high risk for gonorrhoea or Chlamydia(purulent cervical discharge)
- Symptomatic AIDS not on ARV therapy.
- Women with 3rd degree uterine prolapse .
- Women with Vesicovaginal fistulas

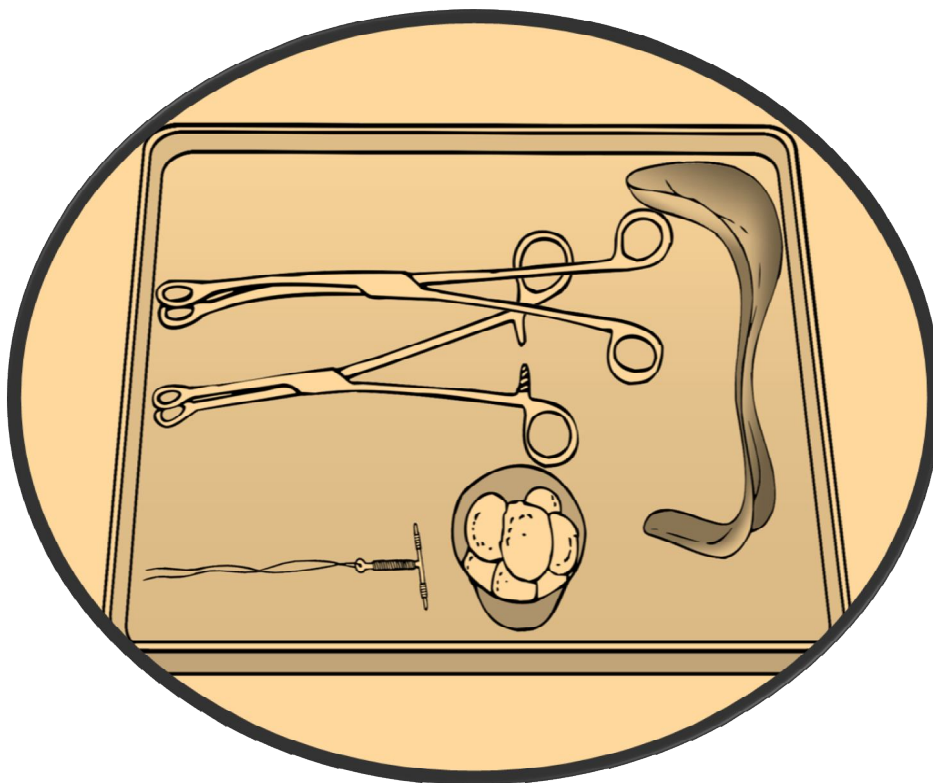
CATEGORY 4: IUCD is contraindicated in

- Pregnant women
- Puerperal sepsis or septic abortion
- With malignant trophoblastic disease.
- Cervical or endometrial/uterine cancer
- Anatomical abnormalities or submucosal myomas that distort the uterine cavity
- Pelvic tuberculosis.
- Unexplained vaginal bleeding .

MATERIALS NEEDED

No extra instruments are needed, except for Kelly's placental forceps, sponge holding forceps, and Sims vaginal retractor.

- Stainless Steel tray with cover
- Kelly's placental forceps
- Sponge holding forceps
- Sim's vaginal retractor
- Disposable surgical gloves
- Antiseptic solution
- Preloaded Copper T380A



TIME OF INSERTION

There are three types of postpartum insertion of intrauterine device.

They are

1. Immediate post placental
 - Insertion within 10 minutes of delivery of the placenta vaginal delivery
 - Intracesarean insertion
2. Within 48 hours of delivery

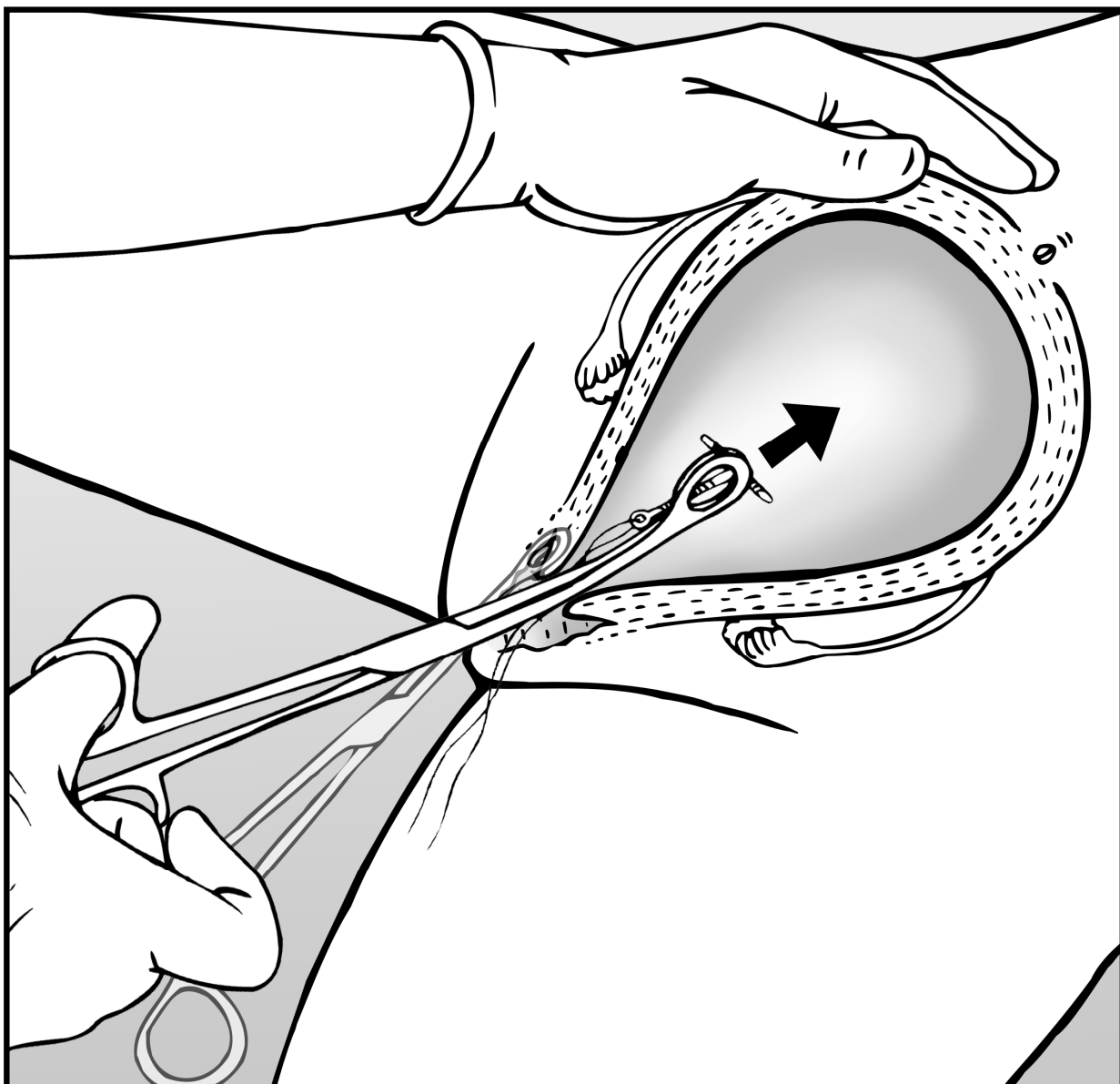
TECHNIQUE OF IUCD INSERTION

- Labour natural-Within 10 minutes of the delivery of the placenta.under strict aseptic precautions, Sims vaginal retractor is taken to retract the vaginal walls and the anterior lip of the cervix is held by the sponge holding forceps, now the preloaded IUCD is inserted into the uterus with the help of Kelly's placental forceps.
- Intracesarean –after the placental delivery and after one third closure of the uterine incision, the IUCD taken in the hand is inserted high up in the fundus of the uterus, the threads are directed towards the sutured uterine wound, and note that thread should not be directed towards the os. Now the remaining two thirds uterine wound is closed in layers.

- 48 hours post partum- Under strict aseptic precautions loaded IUCD is inserted with help of forceps.

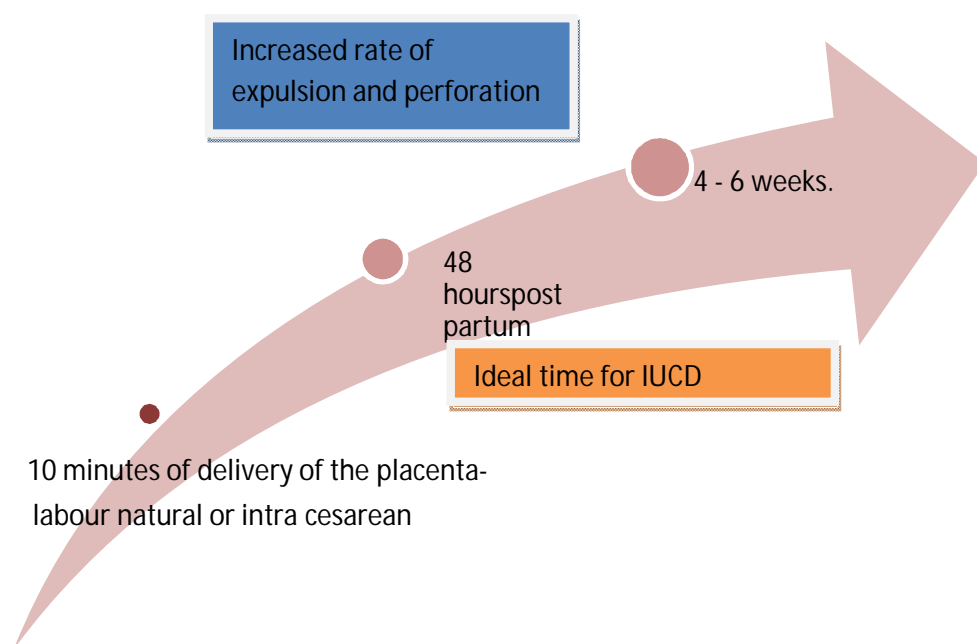
Strict adherence of “no-touch” technique is followed to decrease the risk of infections. Loaded IUCD should not touch the nonsterile surfaces. In all the procedure the threads not trimmed.

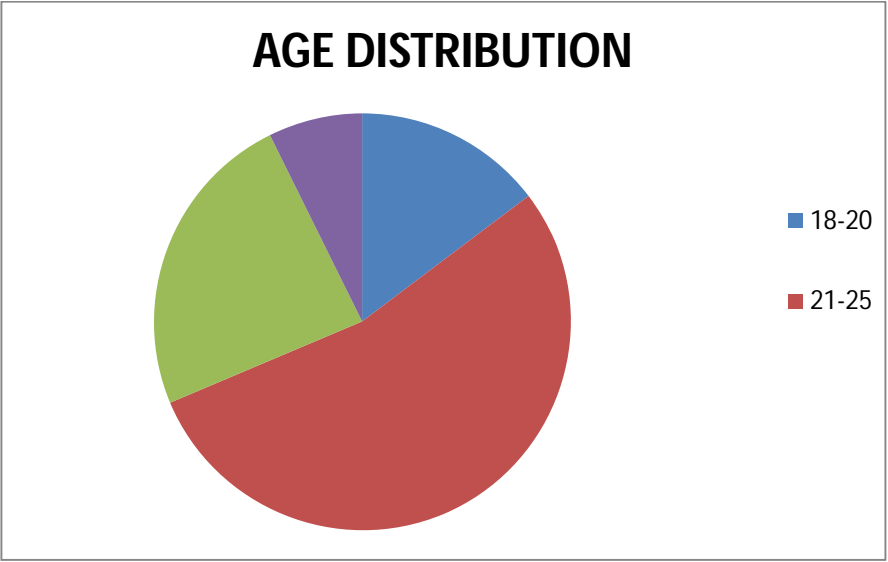




PROPER DISPOSAL

Dispose the waste materials like cotton balls and disposable gloves in a leakproof container .





RESULTS & ANALYSIS

TABLE 1

AGE DISTRIBUTION

AGE GROUP	FREQUENCY	PERCENTAGE
18-20 years	44	14.7
21-25 years	162	54.0
26-30 years	72	24.0
Above 30 years	22	7.3

Among the 300 woman under study majority were in the 21-25 years.
The mean age in this study is 24 years, 54%.

TABLE 2
EDUCATION DISTRIBUTION

EDUCATION	FREQUENCY	PERCENTAGE
Illiterate	24	8.0
Primary school	73	24.3
Middle school	117	39.0
High School	48	16.0
Graduate	38	12.7

In this study, the mean education is middle school.39%

PARITY DISTRIBUTION

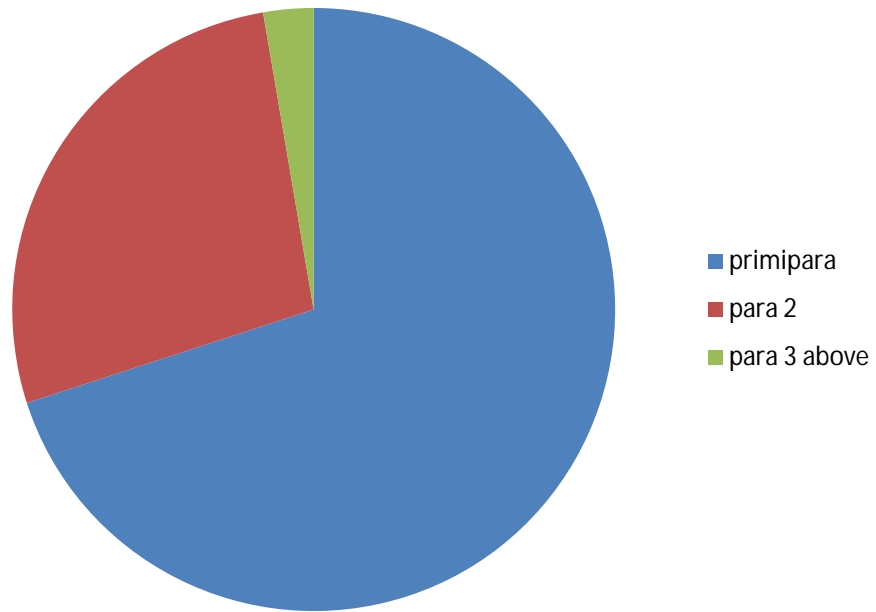


TABLE 3**PARITY DISTRIBUTION**

PARITY	FREQUENCY	PERCENTAGE
Primi para	210	70.0
Para 2	82	27.3
Para 3 and above	8	2.7

The mean parity is primi para 70 %.

TABLE 4**REQUEST / COUNSELLING DISTRIBUTION**

REQUEST / COUNSELLING	FREQUENCY	PERCENTAGE
Patient's request	93	31.0
Husband's request	2	0.7
Counselling	205	68.3

TABLE 5

TIME OF COUNSELLING DISTRIBUTION

TIME OF COUNSELLING	FREQUENCY	PERCENTAGE
Antepartum	99	33.0
Intrapartum	194	64.7
Postpartum	7	2.3

SOCIO ECONOMIC STATUS DISTRIBUTION

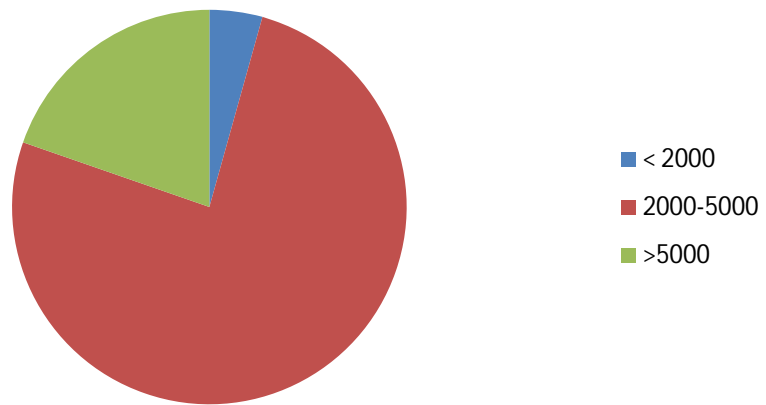


TABLE 6

SOCIOECONOMIC STATUS DISTRIBUTION

INCOME/MONTH	FREQUENCY	PERCENTAGE
< 2000	13	4.3
2000-5000	228	76.0
> 5000	59	19.7

Low income group of less than 2000/month constitutes only 13 members.(4.3%).

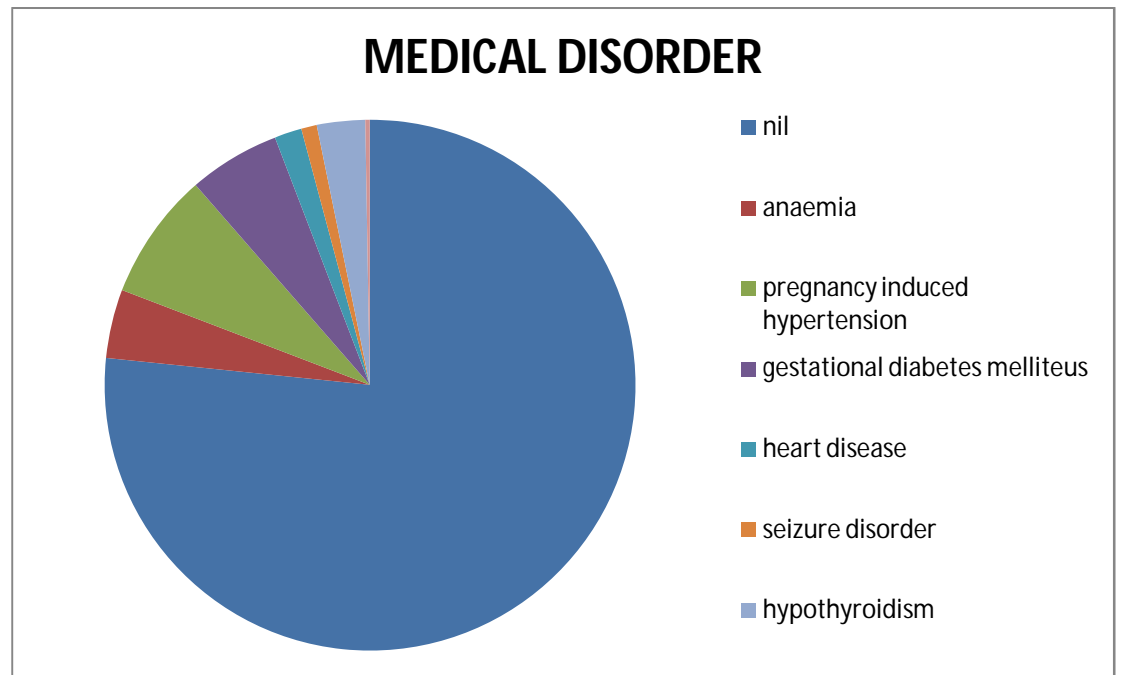


TABLE 7

MEDICAL DISORDER	PERCENTAGE
Nil	78.7
Anaemia	4.3
Pregnancy induced hypertension	8
Gestational diabetes meliteus	5.7
Heart disease	1.7
Seizure disorder	1
Hypothyroidism	3
Residual polio	0.3

TABLE 8
PREVIOUS H/O OF CONTRACEPTIVE USE

PREVIOUS HISTORY OF CONTRACEPTIVE USE	FREQUENCY	PERCENTAGE
None	235	78.3
IUCD	53	17.7
Others	12	4

MODE OF DELIVERY DISTRIBUTION

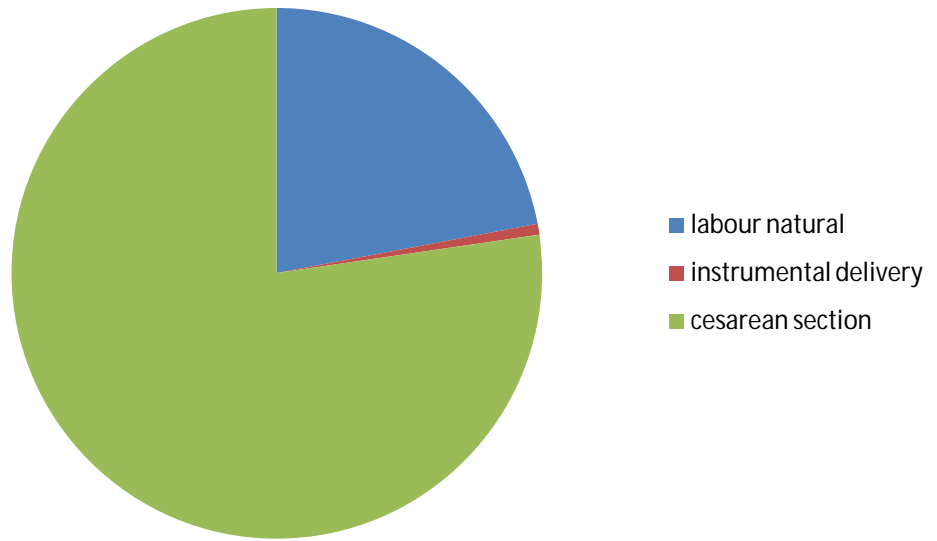


TABLE 9

MODE OF DELIVERY DISTRIBUTION

MODE OF DELIVERY	FREQUENCY	PERCENTAGE
Labour natural	66	22
Instrumental delivery	2	0.7
Caesarean section	232	77.3

In our study, 77.3% were caesarean section and 22% were labour natural.

TIME OF INSERTION DISTRIBUTION

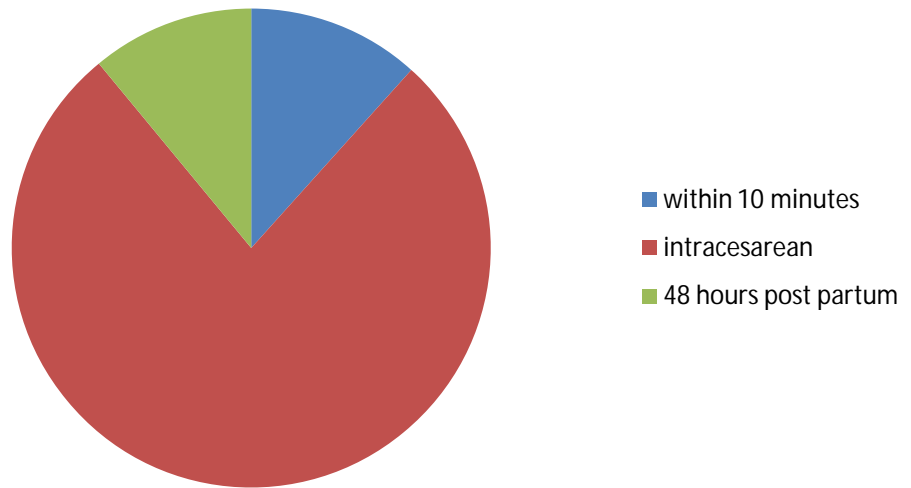


TABLE 10

TIME OF INSERTION DISTRIBUTION

TIME OF INSERTION	FREQUENCY	PERCENTAGE
Within 10 minutes	35	11.7
Intra-cesarean	232	77.3
48 hours postpartum	33	11.0

In this study, 77.3% were intracesarean insertion and among 22% of labour natural only 11.7% insertion were within 10 minutes of placental delivery.

FOLLOW UP DISTRIBUTION

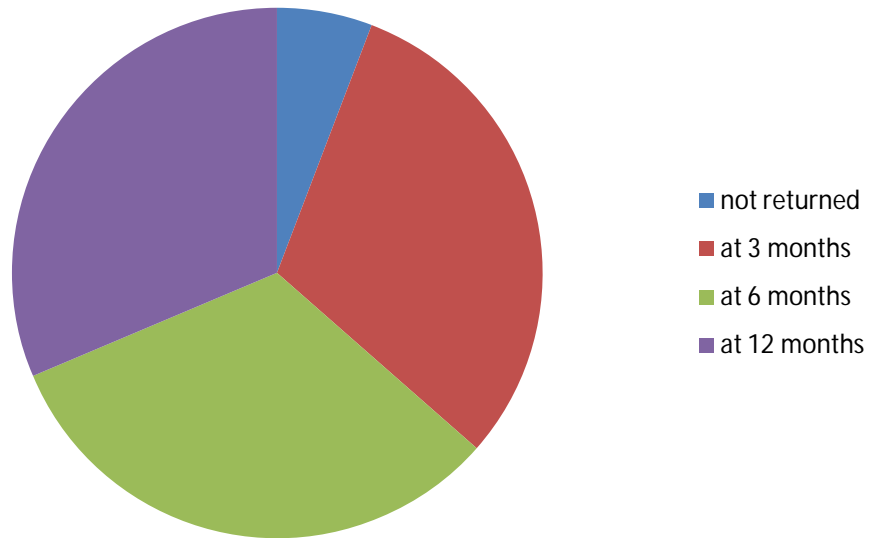


TABLE 11

FOLLOW UP DISTRIBUTION

FOLLOW UP	FREQUENCY	PERCENTAGE
At 3 months	218	72.7
At 6 months	249	76.3
At 12 months	223	74.3
Not returned	41	13.7

Among the 300 woman, only 74.3% followed up at the end of 1 year.not returned for follow up constitutes 41(13.7%).

TABLE 12

REGAINED MENSTRUAL CYCLES

REGAINED MENSTRUAL CYCLES	FREQUENCY	PERCENTAGE
Yes	71	23.7
No	188	62.7

TABLE 13

BREAST FEEDING

BREAST FEEDING	FREQUENCY	PERCENTAGE
Exclusive breast feeding	215	71.7
Combined feeds	44	14.7

COMPLICATIONS DISTRIBUTION

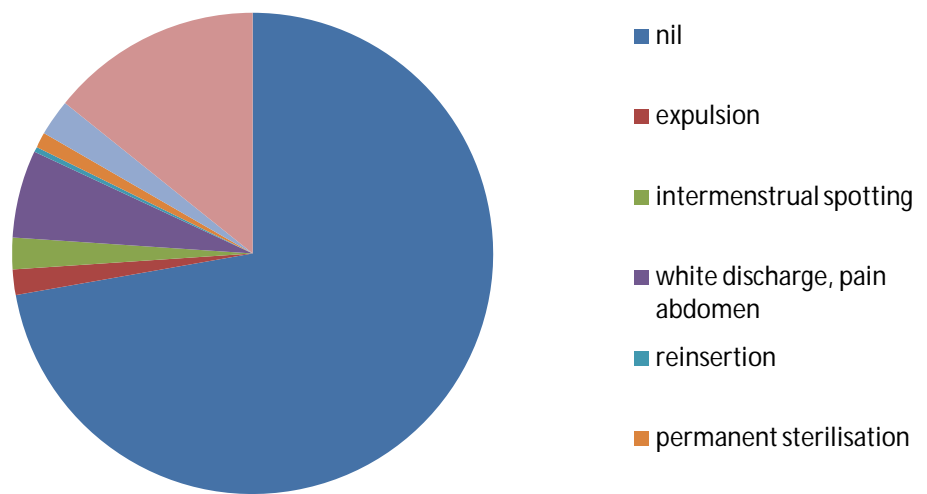


TABLE 14
COMPLICATIONS DISTRIBUTION

COMPLICATIONS	FREQUENCY	PERCENTAGE
Nil	208	69.3
Expulsion followed by no reinsertion	5	1.7
Inter menstrual spotting	18	6.0
White discharge, pain	17	5.7
Expulsion followed by Re - insertion	1	0.3
Permanent sterilisation	3	1.0
Removed	7	2.3

At the end of 12 months , among the 300 woman 41 persons not returned for follow up itself, there are no pregnancy nor perforations.with the cumulative expulsion rate of 1.7% +0.3%=2% and the discontinuation rate is 2.3%.

TABLE 15

THREAD VISIBILITY DISTRIBUTION

THREAD VISIBILTY	FREQUENCY	PERCENTAGE
Yes	150	57.9
No	109	42.1

TABLE 16

MISSING THREAD CONFIRMED BY

ULTRASONOGRAM DISTRIBUTION

MISSING THREAD CONFIRMED BY ULTRASONOGRAM	FREQUENCY	PERCENTAGE
Yes	94	36.2
No	5	1.9

Among 259 woman , 109 (42.1%)woman, Copper T thread was not visible in the follow up on per speculum examination.so transabdominal sonogram was done, to rule out any perforations.in the 109 woman,3 permanent sterilisations, 7 removal were excluded and only for 99 woman trans abdominal sonogram was done.94(36.2%) had CuT was insitu in the uterus.Remaining 5 persons had no Copper T , which confirmed, it was spontaneously expelled and no perforations were there.

TABLE 17**AGE IN GROUPS & COMPLICATIONS****CROSS TABULATION**

COMPLICATIONS	AGE IN GROUPS				TOTAL
	18-20	21-25	26-30	>30	
Nil count	31	113	48	16	208
% of total	79.5%	82.5%	75%	84.2%	80.3%
Expulsion count	0	4	1	0	5
% of total	.0%	2.9%	1.6%	.0%	1.9%
Inter menstrual spotting count	3	3	10	2	18
% of total	7.7%	2.2%	15.6%	10.5%	6.9%
White discharge count	4	10	2	1	17
% of total	10.3%	7.3%	3.1%	5.3%	6.6%
Re-insertion count	0	0	1	0	1
% of total	.0%	0.0%	1.6%	.0%	0.4%
Permanent sterilisation count	0	2	1	0	3
% of total	.0%	1.5%	1.6%	.0%	1.2%
Removed count	1	5	1	0	7
% of total	2.6%	3.6%	1.6%	.0%	2.7%
TOTAL	39	137	64	19	259
	15.1%	52.9%	24.2%	7.3%	100%

According to the above data, as the age increases, there is increased continuation rate with no expulsion and removal, but expulsion & removal rates are high in the 21-25 years age group which is due to the increased pain abdomen and white discharge.

AGE & COMPLICATIONS

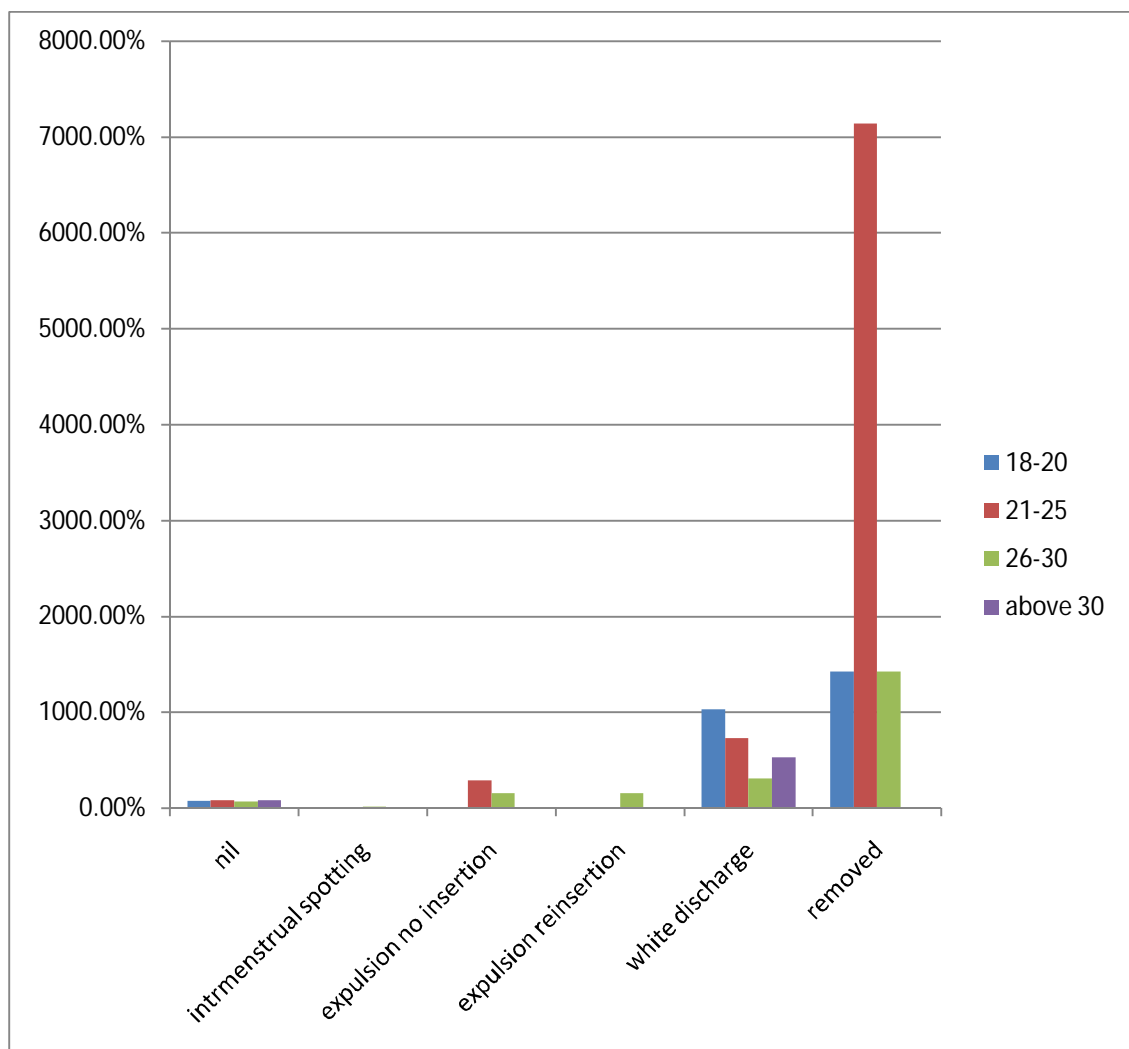


TABLE 18

PARITY & COMPLICATIONS

CROSS TABULATIONS

COMPLICATIONS	PARITY			TOTAL
	Primipara	Para 2	Para 3and above	
Nil count	142	60	6	208
% of total	80.7%	77.9%	100%	80.3%
Expulsion count	4	1	0	5
% of total	2.3%	1.3%	.0%	1.9%
Intermenstrual spotting count	10	8	0	18
% of total	5.7%	10.4%	.0%	6.9%
White discharge count	14	3	0	17
% of total	8.0%	3.9%	.0%	6.6%
Re-insertion count	0	1	0	1
% of total	.0%	1.3%	.0%	0.4%
Permanent sterilisation count	0	3	0	3
% of total	.0%	3.9%	.0%	1.2%
Removed count	6	1	0	7
% of total	3.4%	1.3%	.0%	2.7%
TOTAL	176	77	6	259
	68%	29%	2.3%	100%

According to the above data,removal rate, expulsion rate and white discharge are more with the primiparity.

PARITY & COMPLICATIONS

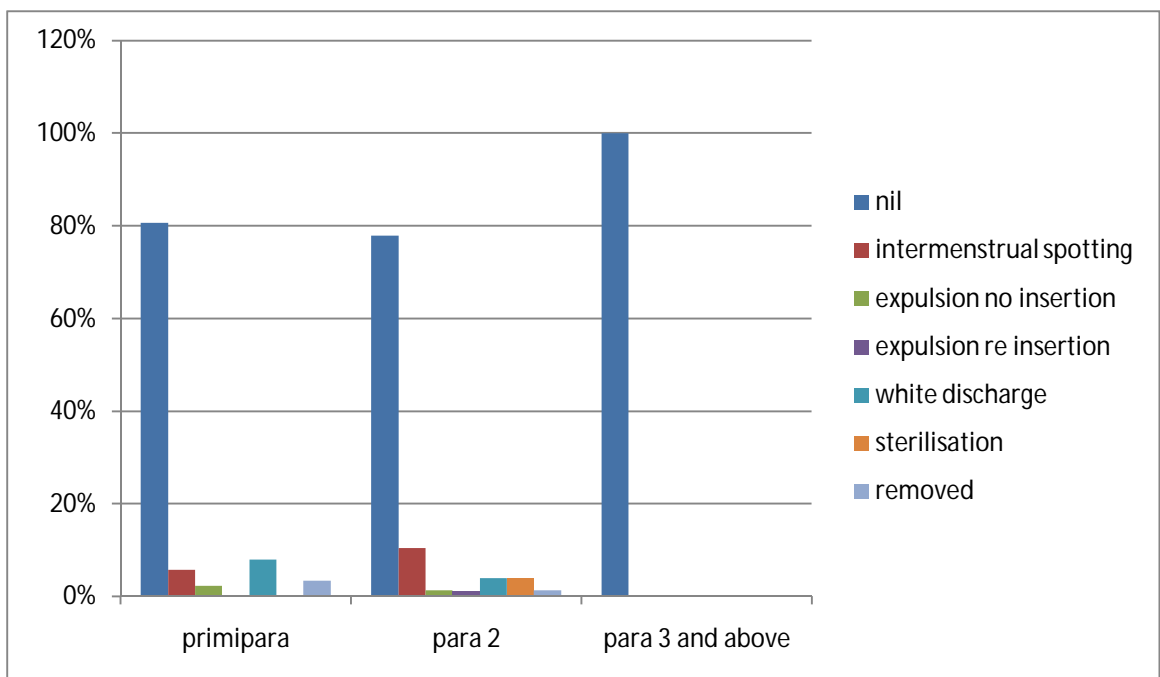


TABLE 19

SOCIOECONOMIC STATUS AND COMPLICATIONS

CROSS TABULATION

COMPLICATIONS	SOCIOECONOMIC STATUS			TOTAL
	<2000	2000-5000	>5000	
Nil count	7	164	37	208
% of total	58.3%	81.6%	80.4%	80.3%
Expulsion count	0	4	1	5
% of total	0%	2%	2.2%	1.9%
Intermenstrual spotting count	2	11	5	18
% of total	16.7%	5.5%	10.9%	6.9%
Lower abdominal pain count	1	14	2	17
% of total	8.3%	7%	4.3%	6.6%
Re- insertion count	1	0	0	1
% of total	8.3%	0%	0%	0.4%
Permanent sterilisation count	1	2	0	3
% of total	8.3%	1%	0%	1.2%
Removed count	0	6	1	7
% of total	0%	3%	3.2%	2.7%
TOTAL	12 4.6%	201 77.6%	46 17.8%	259

According to the above data, there is significant association between socioeconomic status and complications ($p < 0.002$). There are more complications in the lower socioeconomic class. For example, intermenstrual spotting is 16.7% in the < 2000 income group patients, even though they count only 12 members.

SOCIOECONOMIC STATUS & COMPLICATIONS

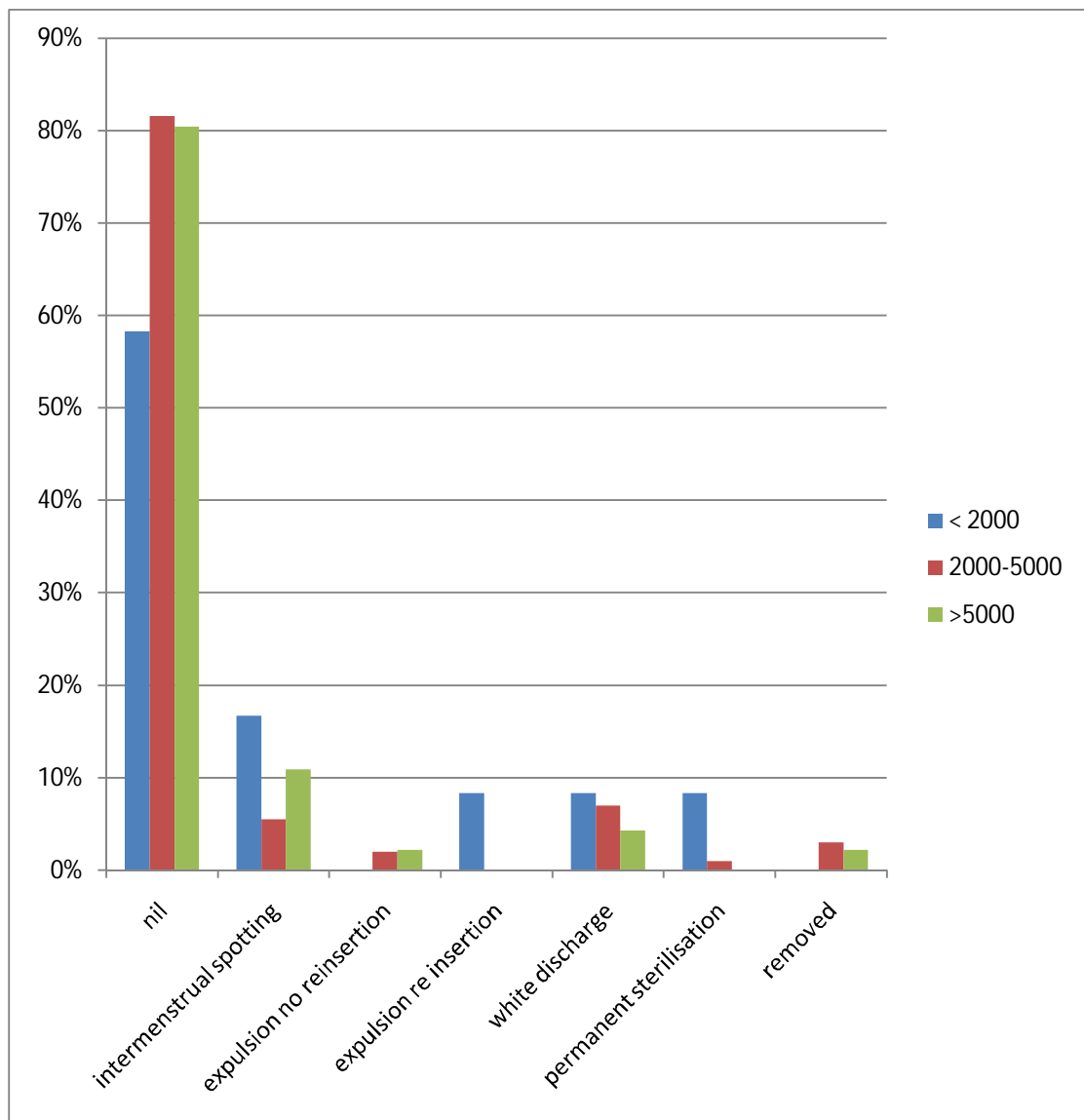


TABLE 20
EDUCATION & COMPLICATIONS

COMPLICATIONS	EDUCATION					TOTAL
	Illiterate	Primary	Middle	High school	Graduate	
Nil count % of total	15 78.9%	62 92.5%	82 79.6%	28 71.8%	21 67.7%	208 80.3%
Intermenstrual spotting count % of total	2 10.5%	2 3%	8 7.8%	2 5.1%	4 12.9%	18 6.9%
Expulsion count % of total	0 .0%	1 1.5%	1 1%	2 5.1%	1 3.2%	5 1.9%
White discharge count % of total	2 10.5%	2 3%	7 6.8%	2 7.7%	3 9.7%	17 6.6%
Expulsion followed reinsertion count % of total	0 .0%	0 .0%	0 .0%	1 2.6%	0 .0%	1 0.4%
Permanent sterilisation count % of total	0 .0%	0 .0%	3 2.9%	0 .0%	0 .0%	3 1.2%
Removed count % of total	0 .0%	0 .0%	2 1.9%	3 7.7%	2 6.5%	7 2.7%
TOTAL	19 7.3%	67 25.9%	103 39.8%	39 15%	31 12%	259 100%

In the above data, the complications are more with the highly educated persons. so education is not a significant factor. $p=0.050$.

TABLE 21

CROSS TABULATION MODE OF DELIVERY &

COMPLICATIONS

COMPLICATIONS	MODE OF DELIVERY			TOTAL
	Labour natural	Instrumental delivery	Cesarean section	
Nil count % of total	55 84.6%	2 100.0%	151 78.6%	208 80.3%
Intermenstrual spotting count % of total	2 3.1%	0 .0%	16 8.3%	18 6.9%
Expulsion not reinsertion count % of total	3 4.6%	0 .0%	2 1.04%	5 1.9%
Expulsion reinsertion count % of total	0 .0%	0 .0%	1 0.5%	1 0.4%
White discharge count % of total	3 4.6%	0 .0%	14 7.3%	17 6.6%
Permanent sterilisation count % of total	1 1.5%	0 .0%	2 1%	3 1.2%
Removed count % of total	1 1.5%	0 .0%	6 3.1%	7 2.7%
TOTAL	65 25.1%	2 0.7%	192 74.1%	259 100%

According to the above data, $p > 0.5$, so mode of delivery is not a significant factor for the development of complications. cesarean delivery has more complications, when compared to labour natural.

MODE OF DELIVERY & COMPLICATIONS

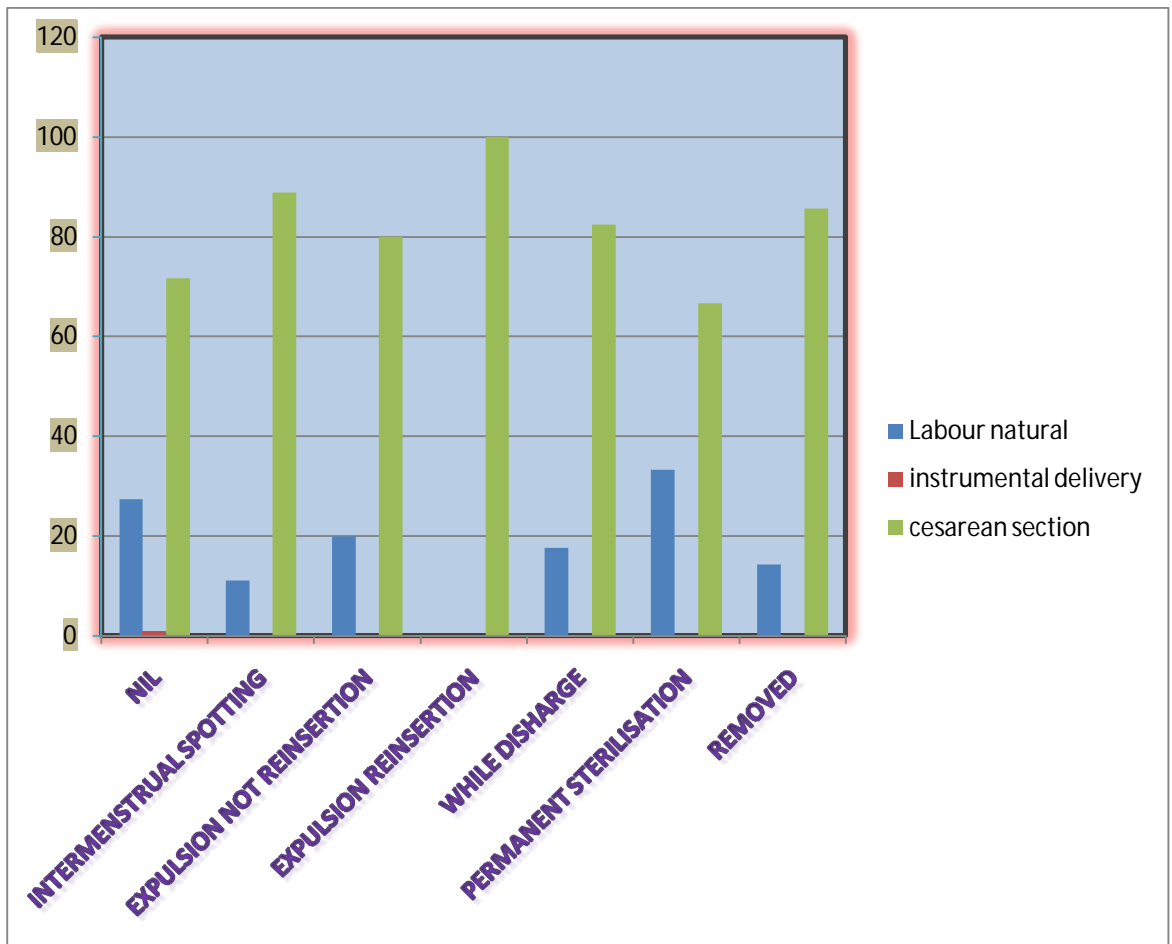


TABLE 22**CROSS TABULATION FOLLOW UP & COMPLICATIONS**

COMPLICATIONS	PERCENTAGE		
	At 3 months	At 6 months	At 12 months
Nil	80.7%	95.6%	93.2%
Intermenstrual spotting	7.3%	5.24%	2.7%
Expulsion no reinsertion	2.3%	-	-
Expulsion reinsertion	0.5%	0.4%	-
White discharge	6.9%	5.24%	2.2%
Permanent sterilisation	0.9%	0.4%	-
removed	1.4%	1.7%	-
TOTAL	72.6%	76.3%	74.3%

Most of the complications occurred in the first 3 months itself, with the cumulative expulsion rate of 2.8% and as the duration from the time of insertion increases, the complication decreases, with the continuation rate of 93.2 % with out any complications.

TABLE 23

CROSS TABULATION TIME OF INSERTION &

COMPLICATIONS

COMPLICATIONS	INTRA-CESAREAN	PERCENTAGE
nil	151	78.6%
Intermenstrual spotting	16	8.4%
Expulsion not reinserted	2	1%
Expulsion reinsertion	1	0.5%
White discharge	14	7.3%
Permanent sterilisation	2	1.0%
Removed	6	3.1%
Total	192	74.1%

From the above data, even though 78.6% of intracesarean insertions have no complications, and expulsion is 1% removal rate is 3.1 %, which is due to medical complications.

TABLE 24

COMPLICATIONS	WITHIN 10 MINUTES	PERCENTAGE
Nil	32	91.4%
Intermenstrual spotting	1	2.9%
Expulsion no reinsertion & reinsertion	0	.0%
White discharge	2	5.8%
removed	0	.0%
Total	35	100%

There are no expulsions and removal rate inspite of woman having intermenstrual spotting 2.9% & white discharge 5.8%.

TABLE 25

COMPLICATIONS	48 HOURS POSTPARTUM	PERCENTAGE
Nil	26	78.8%
Intermenstrual	1	3.0%
Expulsion no reinsertion	3	9%
White discharge	1	3.0%
Permanent sterilisation	1	3.0%
Removed	1	3.0%
Total	33	100%

In this data, among the 33 persons inserted 48 hours postpartum, the expulsion & removal rate is 9% which is high when compared to the intracervical and within 10 minutes insertion.

TABLE 26
CROSS TABULATION EXCLUSIVE BREAST FEEDING
& REGAINED CYCLES

EXCLUSIVE BREAST FEEDING	REGAINED MENSTRUAL CYCLES		TOTAL
	yes	no	
Yes count	52	163	215
% of total	73.2%	86.7%	83%
No count	19	25	44
% of total	26.8%	13.3%	17%
Total	71	188	259
			100%

Out of 259 woman, only 215(83%) have breast fed exclusively for 6 months.

BREAST FEEDING & COMPLICATIONS

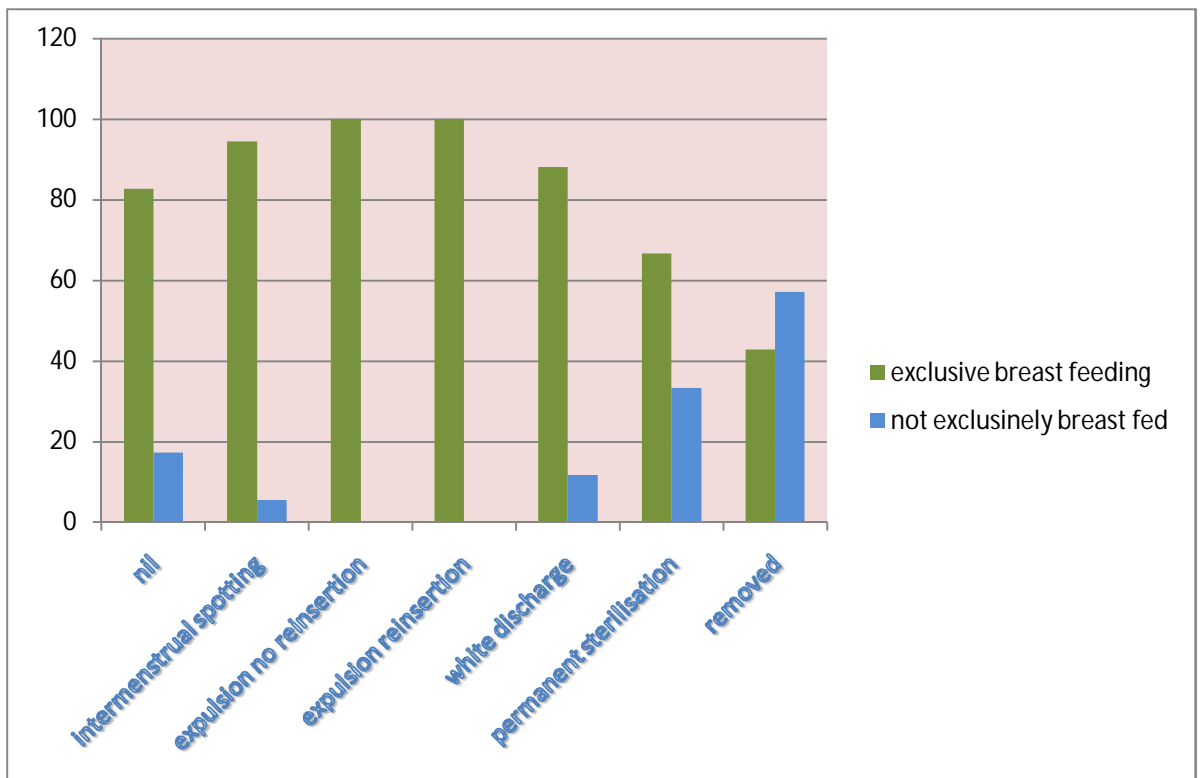


TABLE 27**BREAST FEEDING AND COMPLICATIONS**

COMPLICATIONS	EXCLUSIVE BREAST FEEDING PERCENTAGE	
	yes	no
Nil	82.7%	17.3%
Intermenstrual spotting	94.4%	5.6%
Expulsion no reinsertion	100%	0%
Expulsion reinsertion	100%	0%
White discharge	88.2%	11.8%
Permanent sterilisation	66.7%	33.3%
removed	42..9%	57.1%
Total	83%	17%

Here, the p value is >0.05 . therefore exclusive breastfeeding does not decreases the complications, so it is not significant factor in reducing the complication

TABLE 28**AMENORRHEA AND COMPLICATIONS**

COMPLICATIONS	MENSTRUAL CYCLES PERCENTAGE	
	AMENORRHOEA	REGAINED CYCLES
Nil	86.7%	63.4%
Intermenstrual spotting	-	88.9%
Expulsion no reinsertion	0.5%	5.6%
Expulsion reinsertion	0.0%	1.4%
White discharge	8.5%	1.4%
Permanent sterilisation	0.5%	2.8%
Removed	2.7%	2.8%
Total	72.6%	27.4%

According to the above data, there is significant association between amenorrhea and the reduced complications($p < 0.000$)

TIME OF INSERTION AND THREAD VISIBILITY

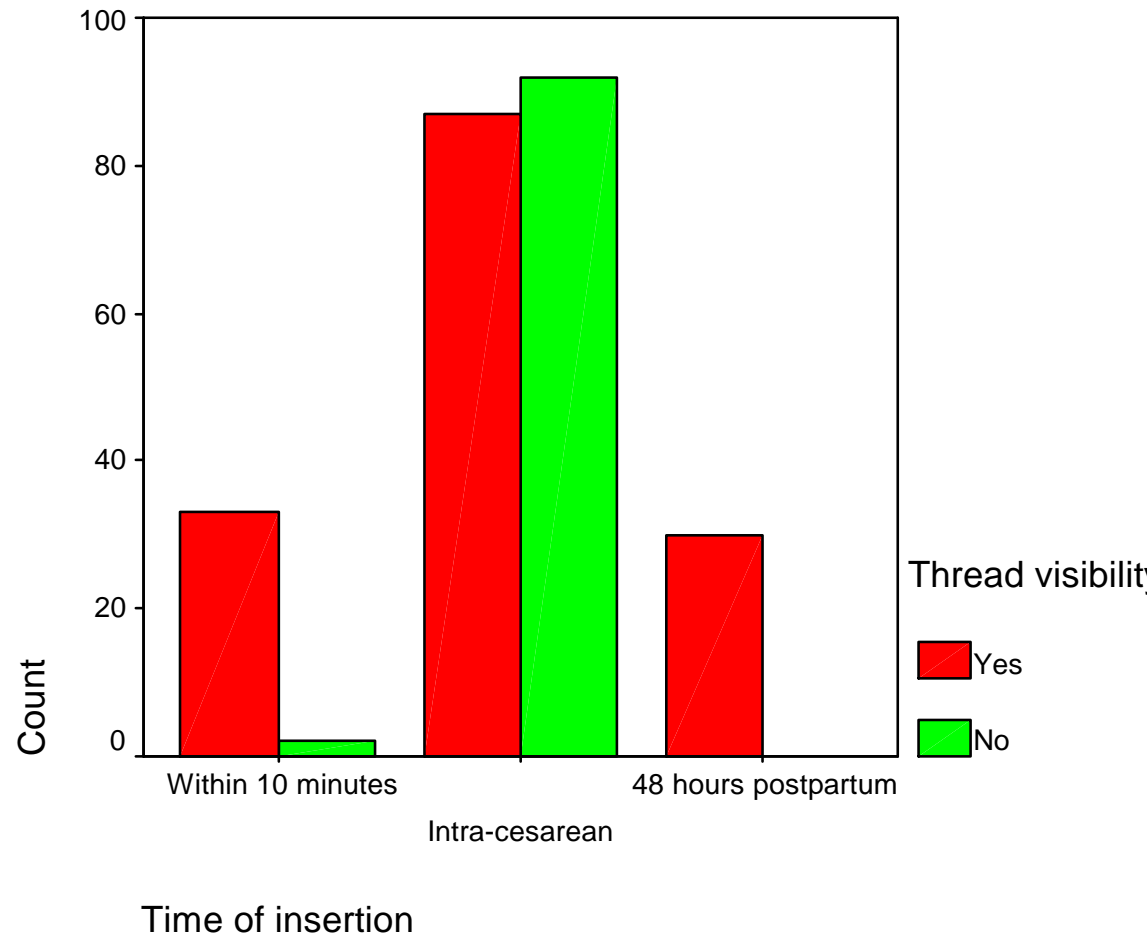


TABLE 29

TIME OF INSERTION AND THREAD VISIBILITY

CROSS TABULATION

TIME OF INSERTION	THREAD VISIBILITY		Total
	Yes	No	
Within 10 minutes count	33	2	35
% of total	94.3%	5.7%	14.3%
Intra-cesarean count	87	92	179
% of total	48.6%	51.4%	73.4%
48 hours postpartum count	30	0	30
% of total	100%	0%	12.3%
Total	150	94	244
	61.5%	38.5%	100%

According to the above data, there is a significant association($p < 0.000$) between time of insertion and thread visibility. within 10 minutes of placental delivery, the IUCD insertion shows increased thread visibility.

TABLE 30

MEDICAL DISORDER WITH COMPLICATIONS.

COMPLICATIONS	PERCENTAGE			
	anaemia	GD M	Heart disease	hypothyroidism
Menstrual problems	18.2	0	20	12.5
expulsion	9.1	14.3	0	0
White discharge	0	14.3	0	25
removed	0	0	20	0

From the above data, the menstrual problems are more in anaemic patients when compared to other medical disorder. $p > 0.5$ it is not statistically significant.

DISSCUSSION

This study highlights the safety and efficacy of postpartum insertion of intra uterine device copper T 380A among the parturitents and followed up for 1 year. Totally 300 woman were included in the study and IUCDS were inserted based on the medical eligibility criteria after getting written informed consent. Insertion of PPIUCD was done after excluding woman who came with draining per vaginum for >12 hours, maternal fever, uterine anamolies, fibroid uterrus, post partum haemorrhage- atonic/traumatic and systemic examination was done given in the proforma.

Out of 300 woman, only 259 returned for follow up..They are given education regarding complications at discharge and counselled for follow up at 3 months and 6months and at 12months.

Almost 218 woman returned for follow up at 3 months, 229 returned at the end of 6 months and 223 at the end of 12 months. During the follow up a detailed history was taken as per the proforma enclosed and thorough general and systemic examination and speculum examination was done for the presence or absence of CopperT inside the uterus by visualisation of the copper T thread. If the threads were missing, then immediate trans abdominal ultrasonogram was done to

identify whether copperT was expelled, or perforated. Out of the 259 persons, we were able to see the threads for 150 women. For remaining 109 clients, threads were not visible. of which 7 removed due to pain abdomen, 3 turned out to permanent sterilisation, and 5 had spontaneous expulsion. so trans abdominal sonogram was done in both remaining 94 women and 5 spontaneous expulsion to see whether IUCD has perforated, embedded in the myometrium or expelled. Findings were, in the 5 spontaneous expulsion women, there was no Copper T inside the uterus. there are neither perforation nor expulsion in the remaining 94 women.

- The mean age of woman in the study was 24 years. About 71.7% of the woman are exclusively breast feeding.
- Followup rate is 74.3%. (i.e) percentage of woman not terminated or returned at the end of 1 year.
- The mean education is middle school.
- The mean age of live birth is primipara.
- Caliskan et al, 2003, analysed the risk factors associated with IUCD insertion. All 8343 women were examined by ultrasound after 1 year. The risk of uterine perforation are more in 0-3 months postpartum than immediate postplacental and after 6 months postpartum with OR 13.2, 11.7 respectively. The risk decreases as

the parity increases OR 0.04. In our study, there were no uterine perforations at the of 12 months as all are immediate postpartum insertion.so also as the parity increases with more than 3 and above, there are no complications.

- literature shows that there are increased risk of uterine perforation in breast feeding women.In our data,there are no perforations during postplacental insertions which was due to the predictable size and consistency of the uterus at these times irrespective of their breast feeding pattern. But all 5 spontaneous expulsion occurred in breast feeding women which may be due to contractility of the uterus secondary to oxytocin and prolactin release.
- Ansari's study shows that uterine perforation caused by an IUD may be secondary to incomplete perforation following primary weakening of the uterine wall due to damage inflicted by the metal sound which is not needed in immediate postpartal insertion of an PPIUCD.
- S evki Celen et al Turkey 2004, Clinical outcomes of early postplacental insertion.i.e. within 10 minutes in vaginal and cesarean deliveries via a ring forceps. Of the 276 patients enrolled, 235 were

included in the study. Recipients were scheduled for examination before hospital discharge and at 6 weeks, 6 months and 12 months after postplacental insertion. The percentages of women returning for a follow-up visit were 221 (94%), 210 (89%) and 183 (78%) at 6 weeks, 6 months and 12 months, respectively. Among IUD acceptors, 74% of the cases had vaginal deliveries and 26% had cesarean deliveries. Continuation rates were relatively high, 87.6% and 76.3%, at 6 and 12 months, respectively. In this study, the 1-year cumulative expulsion rate with TCu 380A device was 12.3%, which may be regarded as a standard expulsion rate for immediate postplacental insertion. In our study, the follow up rate at 3 months, 6 months and at 12 months are 72.6%, 76.3%, 74.3% respectively. The continuation rates at 6 & 12 months are 95.6%, 93.2% respectively. The cumulative expulsion rate is 2%.

SUMMARY

The study was undertaken in 300 parturitents who were willing for PPIUCD. On admission the parturitents were recruited based on the medical eligibility criteria. Women were excluded from the study if they had ruptured membranes for > 12 hours, any haemorrhagic disorder, maternal fever, uterine anomalies, myoma uterus and postpartum haemorrhage. PPIUCD was inserted after getting a written informed consent. The purpose of the study was to determine the safety and efficacy of PPIUCD among the parturitents. Safety means failure rate (pregnancy rate), and efficacy is continuation rate.

A detailed history was elicited as per the proforma enclosed and thorough general and systemic examination was done before PPIUCD insertion and during follow up. The results are interpreted by chi-square tests.

The mean age of woman in the study was 24 years. 54% of women in the study are in the 21-24 years age group. As the number of persons in this group are more, the occurrence of complications will also tend to be higher so age is not a significant factor in determining the efficacy.

In our study only 12 Women (4.6%) belong to the low income group of < 2000 per month . Because of low socioeconomic status, woman in these group have higher incidence of menstrual problems (16.7%), and white discharge (8.3%) which is comparable to the high income group. Also they doesn't want more children, which made them to opt for permanent sterilization (8.3%).so socioeconomic status according to income is a significant factor.(p=0.000) in continuation of IUCD.

In educated persons, the continuation rate should be more when compared to the illiterate persons. But here it is opposite, where the discontinuation rate due to removal is 6.5%.

Most of the complications occurred in the first 3 months of insertion, 2.8% expulsion. When the duration from the time of insertion increases, the complication decreases for example- inter menstrual spotting 7.3% at 3 months decreased to 2.7 % at 12 months of follow up with the continuation rate of 74.3% .

According to the time of insertion intra cesarean insertion has an expulsion rate of 1%, and in 48 hours postpartum has high expulsion rate of 9 %, which may be due to the technique of insertion.

Among 232 intra cesarean insertion, 192 came for follow up, for 51.4% threads were not visible on per speculum examination.

In our study, there are no pregnancy rate nor perforations at the end of 1 year. Efficacy is dependent on the the continuation rate. The discontinuation rate means it includes both spontaneous expulsion and removal due to medical problems.

Cumulative expulsion 2%.(1.7+0.3%)

Cumulative Removal rate 2.3%

Menstrual complaints 6%

CONCLUSION

Our study highlights the following,

- There is no significant association between age, parity, or education and the efficacy of PPIUCD.
- Women from low socioeconomic group has increased incidence of menstrual problems and white discharge .
- Even though 48 hours postpartum is safe for IUCD insertion, there are 9% expulsion rate, when compared to immediate within 10 minutes insertion (includes intracesarean-1%, following labour natural – nil) expulsion.so it signifies that the technique and time of insertion plays a significant factor in the continuation rate.
- As there are no untoward complications like pregnancy nor perforations with minimal expulsion rate of 1.7% and removal rate of 2.3%, PPIUCD is the most safe and highly efficacious mode of population control and provides a healthy birth spacing,there by decreasing the unmet need for family planning.

- Majority of the PPIUCD were inserted after proper counseling (68%), only 0.3% underwent reinsertion following spontaneous expulsion, which indicates that even more information regarding the advantages and disadvantages of the all available methods and PPIUCD have to be explained to decrease the unmet need of the family planning services.

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ABBREVIATIONS

PPIUCD	-	Postpartum insertion of intrauterine device
IUCD	-	Intrauterine device.
NFHS	-	National Family Health Survey
GOI	-	Government of India
OCP	-	Oral contraceptive pills
JHPIEGO	-	Johns Hopkins Program for International Education in Gynaecology and Obstetrics.
CuT	-	Copper T
OR	-	Odds ratio
MEC	-	Medical Eligibility Criteria
ICMR	-	Indian Council of Medical Research
NSAID'S	-	NonSteroidal Anti inflammatory Drugs
LNG	-	Levonorgestrol
CI	-	Confidence Limits
MLCu	-	Multiload copper
EP	-	Early postpartum
IPP	-	Immediate postplacental
INT	-	Interval
PID	-	Pelvic inflammatory disease

PROFORMA

SERIAL NO.

HOSPITAL NO.

Name	:	Address	:
Age	:	Education	:
Socioeconomic status	:	Occupation	:
Obstetric score	:		
Present history	:		
Menstrual history	:	age of menarche,regular/irregular cycles	
Marital history	:		
Obstetric history	:		
Previous history of			
contraceptive use	:		
Past history	:		
Personal history	:		
Counselling	:	antepartum/intrapartum	

General examination :

- Afebrile
- Anaemic/not
- No pedal edema
- Vitals-Temp, Pulse rate, RR, Blood Pressure
- CVS/RS- normal
- According to the mode of delivery- PPIUCD is inserted.

Investigations:

Urine –albumin, sugar , deposits

Complete hemogram

Renal,liver function tests

Blood grouping & typing.

On discharge:

After thorough general examination, per speculum examination is done. Only for 48 hours postpartum, threads are trimmed.

Advice given on exclusive breast feeding,

- any lower abdominal pain
- abnormal discharge
- fever
- expulsion
- To come for follow up at 3months, 6months and 12 months.

PROFORMA FOR FOLLOW UP

Name

Age

Follow up	At 3 months	At 6 months	At 12 months

Parity

Complaints of:

- spotting/bleeding per vaginum
- dysmenorrhoea
- lower abdominal pain

- low backache
- White discharge
- Expulsion
- Causes for removal
- Perforation
- Pregnancy.

Breast feeding: Exclusively/not. How long. What are the alternatives given.

Menstrual history:

Regained cycles/not. If regained cycles- when, flow.

Spotting/bleeding, associated with pain abdomen, any inter menstrual disturbances present.

General examination:

- Afebrile
- Anaemic
- Pedal edema
- Vitals- temperature, BP, pulse,
- CVS/RS
- Per abdomen examination: warmth, tenderness, uterine size- involution
- Per speculum examination- lochia, abnormal discharge, thread visible/not. If visible the threads are trimmed.

If threads are not visible, they are subjected to trans abdominal examination – to rule out expulsion and perforation

CONSENT FORM

STUDY TITLE : **EFFICACY AND SAFETY OF PPIUCD
AMONG PARTURIENTS**

STUDY CENTRE : Institute of Social obstetrics and Govt., KGH,
Chennai

Participant Name : **Age :** **Sex:** **I.P.No**

I confirm that I have understood the purpose of procedure for the above study, I have the opportunity to ask the question and all my questions and doubts have been answered to my satisfaction.

I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving any reason.

I understand that investigator, regulatory authorities, and the ethics committee will not need my permission to look at my health records both in respect to the current study and any further research that may be conducted in relation to it, even if I withdraw from the study. I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law. I agree not to restrict the use of any or results that arise from the study.

I hereby consent to participate in this study of **efficacy and safety of ppiucd among parturitents**

Signature of Investigator:

Place:

Date :

Study Investigators Name

Institution

Signature /Thumb Impression of patient

Place :

Date :

Signature of witness

சுய ஒப்புதல் படிவம்

- ஆய்வு செய்யப்படும் தலைப்பு - பிரசவித்த பின் நடுக்கொடி பிரிந்தபின்பு தற்காலிக கருத்தடை முறையான "கருத்தடை வளையம்" பொருத்துதல்.
- ஆராய்ச்சி நிலையம் - சமூக மகப்பேறியல் மற்றும் அரசு கஸ்தூரிபாய் காந்தி தாய்சேய் நல மருத்துவமனை சென்னை மருத்துவக் கல்லூரி மற்றும் மருத்துவமனை, சென்னை - 600003.
- பங்கு பெறுபவரின் பெயர் -
- பங்கு பெறுபவரின் எண் -

மேலே குறிப்பிட்டுள்ள மருத்துவமனை ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது. என்னுடைய சந்தேகங்களை கேட்கவும், அதற்கான தகுந்த விளக்கங்களை பெறவும் விளக்கப்பட்டுள்ளது.

நான் இவ்வாய்வில் தன்னிச்சையாகதான் பங்கேற்கிறேன். எந்த காரணத்தினாலோ எந்த சட்ட சிக்கலுக்கும் உட்படாமல் நான் இவ்வாய்வில் இருந்து விலகி கொள்ளலாம் என்றும் அறிந்து கொண்டேன்.

இந்த ஆய்வு சம்மந்தமாகவோ, இதை சார்ந்த மேலும் ஆய்வு மேற்கொள்ளும்போதும் இந்த ஆய்வில் பங்குபெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளை பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்து கொள்கிறேன். நான் ஆய்வில் இருந்து விலகிக் கொண்டாலும் இது பொருந்தும் என அறிகிறேன்.

இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும், பரிசோதனை முடிவுகளையும் மற்றும் சிகிச்சை தொடர்பான தகவல்களையும், மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்திக் கொள்ளவும் அதை பிரசுரிக்கவும் என்முழு மனதுடன் சம்மதிக்கிறேன்.

இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக் கொள்கிறேன். எனக்கு கொடுக்கப்பட்ட அறிவுரைகளின்படி நடந்து கொள்வதுடன் இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்றும் உறுதியளிக்கிறேன். என் உடல் நலம் பாதிக்கப் பட்டாலோ அல்லது எதிர்பாராத வழக்கத்திற்கு மாறான நோய்க்குறி தென்பட்டாலோ உடனே அதை மருத்துவ அணியிடம் தெரிவிப்பேன் என உறுதி அளிக்கிறேன்.

பங்கேற்பவரின் கையொப்பம்.....இடம்..... தேதி.....

கட்டை விரல் ரேகை

பங்கேற்பவர் பெயர் மற்றும் விலாசம்

ஆய்வாளரின் கையொப்பம் இடம்..... தேதி.....

ஆய்வாளரின் பெயர்

தகவல் படிவம்

- ஆய்வு செய்யப்படும் தலைப்பு - பிரசுவித்த பின் நஞ்சுகொடி பிரிந்தபின்பு
தற்காலிக கருத்தடை முறையான "கருத்தடை
வளையம்" பொருத்துதல்.
- ஆய்வாளர் - மருத்துவர் பி.காமாட்சி காயத்ரி
சமூக மகப்பேறியல் மற்றும் அரசு கஸ்தூரிபாய்
காந்தி தாய்சேய் நல மருத்துவமனை
சென்னை மருத்துவக் கல்லூரி மற்றும்
மருத்துவமனை, சென்னை - 600003.

இந்த ஆய்வில் பங்கு பெறுவது நோயாளிகளின் சொந்த விருப்பத்திலேயே ஆகும்.
இந்த ஆய்வினால் நோயாளிகளுக்கு எந்த செலவும் இருக்காது. இந்த ஆய்வையொட்டி
எந்தவிதமான சந்தேகங்களுக்கும் விளக்கம் பெற நோயாளிகளுக்கு உரிமை உள்ளது.
இந்த ஆய்வின் முடிவுகள் இறுதியில் பிரசுரிக்கப்படும்.